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Ming H. Wu

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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,466	Applicant(s) WU ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 and 31-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/2004, 10/14/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 22 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox (US 6,375,676).

Regarding claim 22, Cox discloses a nickel-titanium alloy composition comprising about 55.5 weight percent of nickel based on the total composition of the alloy (col. 14, lines 1-4).

Regarding claim 26, Cox discloses a stent manufactured from the composition of claim 22 (col. 14, lines 1-4).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6, and 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flomenblit et al. (US 5,624,508) in view of Hossainy (US 6,153,252).

Regarding claim 1, Flomenblit et al. disclose a medical device comprising:
a shape memory alloy having a reverse martensitic transformation start

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temperature (A_s) greater than or equal to about 0 degrees Celsius (col. 5, ln. 39-43). Flomenblit et al. lack a drug coating comprising a polymeric resin and one or more biologically active agents. Hossainy et al. disclose coating a nickel-titanium alloy stent with a drug coating comprising a polymeric resin and one or more biologically active agents (col. 7, ln. 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Flomenblit with the drug coating comprising a biologically active agent as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis (col. 1, ln. 12-24).

Regarding claims 2, 3, and 4, Flomenblit et al. disclose the shape memory alloy has a reverse martensitic transformation start temperature between 1 and 5 degrees Celsius less than the transformation finish temperature (A_f) which can range between 10 and 60 degrees Celsius (col. 5, ln. 39-43). Flomenblit et al. disclose the claimed invention except for the transformation start being about 10 to 15 degrees Celsius or greater than or equal to 20 Celsius and transformation finish temperature being about 25 to 50 degrees Celsius. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum ranges for both the transformation start and transformation finish temperatures, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 5, Flomenblit et al. disclose the shape memory alloy is a nickel-titanium alloy (col. 7, lines 5-7).

Regarding claim 6, Flomenblit et al. disclose the nickel-titanium based alloy is a binary nickel-titanium alloy, nickel-titanium-niobium alloy, nickel-

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titanium-copper alloy, nickel-titanium-iron alloy, nickel-titanium-hafnium alloy, nickel-titanium-palladium alloy, nickel-titanium-gold alloy, nickel-titanium-platinum alloy, or comprising at least one of the foregoing nickel-titanium based alloys (col. 7, lines 5-7) .

Regarding claim 10, Hossainy et al. fail to disclose the glass transition temperature less than or equal to a reverse martensitic transformation start temperature of the shape memory alloy. However, Hossainy et al. discloses that the polymeric coating should not crack during the expansion of the stent (col. 5, ln. 39-51). Therefore, one of ordinary skill in the art would have provided a polymeric resin having a glass transition temperature less than or equal to the reverse martensitic transformation start temperature so that the coating would not crack during expansion.

Regarding claim 11, Hossainy et al. disclose the polymeric resin is a thermoplastic resin, thermosetting resin or a blend of a thermoplastic resin with a thermosetting resin (col. 5, ln. 39-51).

Regarding claim 12, Hossainy et al. disclose thermoplastic resin is polyacetal, polyacrylic, polycarbonate, polystyrene, polyethylene, polypropylene, polyethylene terephthalate, polybutylene terephthalate, polyamide, polyamideimide, polybenzimidazole, polybenzoxazole, polybenzothiazole, polyoxadiazole, polythiazole, polyquinoxaline, polyimidazopyrrolone, polyarylate, polyurethane, polyarylsulfone, polyethersulfone, polyphenylene sulfide, polyvinyl chloride, polysulfone, polyetherimide, polytetrafluoroethylene, fluorinated ethylene propylene, perfluoroalkoxy polymer, polychlorotrifluoroethylene, polyvinylidene fluoride, polyvinyl fluoride, polyetherketone, polyether etherketone,

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polyether ketone or a combination comprising at least one of the foregoing thermoplastic resins (col. 5, ln. 6-37).

Regarding claim 13, Hossainy et al. disclose the thermosetting resin is a polyurethane, natural rubber, synthetic rubber, epoxy, phenolic, polyester, polyamide, silicone, or a combinations comprising at least one of the foregoing thermosetting resin (col. 5, ln. 6-37).

Regarding claim 14, Hossainy et al. discloses the drug coating comprises an amount of about .001 weight percent to about 70 weight percent of the biologically active agent based on total weight of the drug coating (col. 9, ln. 20-25). Hossainy et al. disclose the claimed invention except for the drug coating comprising an amount of about 5 weight percent to about 90 weight percent of the biologically active agent based on the total weight of the drug coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum amount of the biologically active agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 15, Hossainy et al. disclose the biologically active agents are dispersed within the polymeric resin (col. 8, ln. 36-67).

Regarding claim 18, Hossainy et al. disclose the polymeric resin is a biodegradable polymer having different degradability rates in order to control the release of drugs at various rates and times or to release multiple drugs with different pharmaceutical behaviors (col. 7, ln. 17-55).

Regarding claim 19, Hossainy et al. disclose wherein the biodegradable polymer is a polylactic-glycolic acid, poly-caprolactone, copolymer of polylactic-

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glycolic acid and poly-caprolactone, polyhydroxy-butyrates-valerate, polyorthoester, polyethyleneoxide-butylene terephthalate, poly-D,L-lactic acid-p-dioxanone-polyethylene glycol block copolymer or a combination comprising at least one of the foregoing biodegradable polymers (col. 4, ln. 15-67).

Regarding claim 20, Flomenblit et al. disclose the device is an implantable device (col. 7, lines 24-25).

Regarding claim 21, Flomenblit et al. disclose the implantable device is a stent, bone staple, a vena cava filter, a suture, or an anchor-like mechanism (col. 7, lines 24-25).

5. Claims 1, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Besselink et al. (US 6,428,634) in view of Hossainy et al. (US 6,153,252).

Regarding claim 1, Besselink et al. disclose a medical device comprising a shape memory alloy. Besselink discloses that it is well known to modify Ni-Ti-Nb based alloys so that the alloys can be stored in a martensite phase at room temperature (col. 1, ln. 62 – col. 2, ln. 4). Therefore, it would have been obvious to one of ordinary skill in the art to have a transformation start temperature greater than room temperature so that the alloys can be stored in martensitic phase at room temperature. Besselink et al. lack a drug coating comprising a polymeric resin and one or more biologically active agents. Hossainy et al. disclose coating a nickel-titanium alloy stent with a drug coating comprising a polymeric resin and one or more biologically active agents (col. 7, ln. 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Besselink et al. with a drug coating comprising a polymeric resin and one or more biologically active agents

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as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis (col. 1, ln. 12-24).

Regarding claim 7, Besselink et al. disclose the nickel-titanium based alloy is a nickel-titanium-niobium alloy comprising about 4 to about 43 percent Niobium and the ratio of nickel to titanium is from about .8 to 1.2 (see abstract). Besselink et al. discloses the claimed invention the alloy comprising about 30 to 56% nickel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum nickel composition, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 9, Besselink et al. disclose the nickel-titanium based alloy is a nickel-titanium-niobium alloy comprising about 4 to about 14 % Niobium and the ratio of nickel to titanium is from about .8 to 1.2 (see abstract). Besselink et al. discloses the claimed invention the alloy comprising about 48% nickel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum nickel composition, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

6. Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flomenblit et al. (US 5,624,508) in view of Le Moel et al. (US 6,517,858).

Regarding claim 1, Flomenblit et al. disclose a medical device comprising: a shape memory alloy having a reverse martensitic transformation start temperature (A_s) greater than or equal to about 0 degrees Celsius (col. 5, ln. 39-

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43). Flomenblit et al. lack a drug coating comprising a polymeric resin and one or more biologically active agents. Le Moel et al. disclose coating a metallic stent with a drug coating comprising a polymeric resin and one or more biologically active agents (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Flomenblit with the drug coating comprising a biologically active agent as taught by Le Moel et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis.

Regarding claim 15, Le Moel et al. disclose the biologically active agents are copolymerized with the polymeric resin (col. 5, ln. 52-60 and claim 20).

7. Claims 1 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flomenblit et al. (US 5,624,508) in view of Hossainy (US 6,790,228).

Regarding claim 1, Flomenblit et al. disclose a medical device comprising: a shape memory alloy having a reverse martensitic transformation start temperature (A_s) greater than or equal to about 0 degrees Celsius (col. 5, ln. 39-43). Flomenblit et al. lack a drug coating comprising a polymeric resin and one or more biologically active agents. Hossainy et al. disclose coating a nickel-titanium alloy stent with a drug coating comprising a polymeric resin and one or more biologically active agents (see abstract and col. 16, ln. 59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Flomenblit with the drug coating comprising a biologically active agent as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis.

Regarding claim 16, Hossainy et al. disclose biologically active agents encapsulated between layers of polymeric resins (col. 20, ln. 3-29; Fig. 2).

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8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Hossainy et al. (US 6,153,252).

Regarding claim 27, Cox discloses the claimed invention except for the stent coated with a drug coating comprising a biologically active agent. Hossainy et al. disclose coating a nickel-titanium alloy stent with a drug coating comprising one or more biologically active agents (col. 7, ln. 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Cox with a drug coating comprising a biologically active agent as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis (col. 1, ln. 12-24).

9. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Besselink et al. (US 6,428,634).

Regarding claim 28, Besselink et al. disclose the nickel-titanium based alloy is a nickel-titanium-niobium alloy comprising about 4 to about 14 % Niobium and the ratio of nickel to titanium is from about .8 to 1.2 (see abstract). Besselink et al. discloses the claimed invention the alloy comprising about 48% nickel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum nickel composition, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 29, Besselink et al. disclose a stent manufactured from the composition of claim 28 (col. 4, ln. 64).

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Besselink et al. (US 6,428,634), and further in view of Hossainy et al.

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Regarding claim 30, Besselink et al. fails to disclose the stent is coated with one or more drug coatings having biologically active agents. Hossainy et al. disclose coating a nickel-titanium alloy stent with a drug coating comprising one or more biologically active agents (col. 7, ln. 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Besselink et al. with a drug coating comprising a biologically active agent as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis (col. 1, ln. 12-24).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L. H./
Examiner, Art Unit 3734

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

jlh
3/27/08